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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/156,580	09/18/98	TAKATSUJI	H 085761-0004

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1649	11

DATE MAILED: 08/18/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/156,580	TAKATSUJI et al
Examiner	**Group Art Unit**
Ashwin Mehta	1649

☒ Responsive to communication(s) filed on *Jun 1, 1999*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-9* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-9* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn toward a gene having DNA having nucleotides 190-807 from SEQ ID NO: 1, or any DNA which hybridizes to it and encodes any transcription factor capable of altering any character of a plant; or a gene encoding a transcription factor having the amino acid sequence set forth in SEQ ID NO: 2, or having the amino acid sequence of SEQ ID NO: 2 wherein one or more amino acids are subjected to deletion, substituion, or addition, and being capable of altering any character of a plant; methods for producing a transgenic plant comprising introducing said gene into a plant cell; and the resultant transgenic plant.

The only gene described by specification which encodes a transcription factor capable of altering the height and internode length of a plant upon introduction into a plant is that set forth in SEQ ID NO: 1, and which encodes the amino acid sequence of SEQ ID NO: 2. Other genes encoding DNA which hybridize to nucleotides 190-807 of SEQ ID NO: 1, or encode the amino acid sequence of SEQ ID NO: 2 wherein one or more amino acids are subject to deletion, substitution, or addition, and which can alter any characteristic of a plant, are not described by the specification. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not obtained until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence), and at page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof. Also see *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states: "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA... Accordingly, the specification does not provide a written description of the invention..." Given the breadth of the claims encompassing genes encoding substitutions, deletions and additions of amino acid sequences of SEQ ID NO: 2, and genes encoding DNA which hybridize to nucleotides 190-807 of SEQ ID

NO: 1, and the lack of guidance as discussed above, the specification fails to provide an adequate written description of the multitude of nucleotide sequences encompassed by the claims.

2. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn toward a gene having DNA having nucleotides 190-807 from SEQ ID NO: 1, or any DNA which hybridizes to it and encodes any transcription factor capable of altering any character of a plant; or a gene encoding a transcription factor having the amino acid sequence set forth in SEQ ID NO: 2, or having the amino acid sequence of SEQ ID NO: 2 wherein one or more amino acids are subjected to deletion, substituion, or addition, and being capable of altering any character of a plant; methods for producing a transgenic plant comprising introducing said gene into a plant cell; and the resultant transgenic plant.

The specification does not teach any genes that hybridize to nucleotides 190-807 of SEQ ID NO: 1, nor genes encoding variations of SEQ ID NO: 2, and which are capable of altering any character of a plant. The specification does not reveal the changes to the nucleotide sequence that define these sequences which hybridize to SEQ ID NO: 1 or encode variants of SEQ ID NO: 2. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., *supra*. Also see In re Bell, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and In re Deuel, 34 UPSQ2d, 1210 (Fed. Cir. 1995), which teach that the mere existence of a protein does not enable claims drawn to a nucleic acid encoding that

protein. It would require undue experimentation by one skilled in the art to produce, define, and evaluate these variants for conservation of enzymatic function. Given the claim breadth encompassing deletions, substitutions, or additions of the amino acid sequence of SEQ ID NO: 2, and DNA which hybridizes to SEQ ID NO: 1, unpredictability of the art and lack of guidance of the specification, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 1-9 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "having" renders claim 1 indefinite. It is not clear what other nucleotide sequences are present in the claimed gene. It is also not clear what other DNA sequences besides nucleotides 190-807 of SEQ ID NO: 1 are present in the DNA of part a).

Claim 1 is also indefinite because the stringent conditions of part b) are not defined. It is also unclear what "characters of a plant" are being referred to in claim 1, part b).

Claim 2 is also indefinite because it is unclear what "characters of a plant" are being referred to in part ii).

Claim 4 is also indefinite because it is unclear whether "plant body" refers to a plant part or an entire differentiated plant. If the recitation only refers to a plant part, then the last step of the claimed method would not be producing a transgenic plant.

Claim Objections

4. Claim 3 is objected to because of the recitations "a height of a plant" and " a length of an internode", as there can be only one height and length at any particular time. The claim would be clearer if the recitations were amended to read --the height-- and --the length--.

5. Claim 4 is objected to for the recitation "introducing a plant...the introduced gene". The recitation would be clearer and more precise if it were amended to read --introducing the gene of claim 1 into a plant cell, and regenerating the plant cell into a transgenic plant--.

6. Claim 5 is objected to because the recitation "the plant belongs to dicotyledon" is not precise. It is suggested that the recitation be amended to read --the plant is a dicotyledon--.

7. Claim 6 is objected because the recitation "the plant belongs to Solanaceae" is not precise. It is suggested that the recitation be amended to read --the plant is a member of the Solanaceae family--.

8. Claim 7 is objected to because the recitation "the plant belongs to Petunia" is not precise. It is suggested that the recitation be amended to read --the plant is a member of the *Petunia* genus--.

9. Claims 1-9 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest the isolated nucleotide sequence set forth in SEQ ID NO: 1, or a gene encoding a transcription factor with the amino acid sequence set forth in SEQ ID NO: 2, from *Petunia hybrida*.

CLOSING REMARKS

Any inquiry concerning this communication should be directed to Examiner Ashwin Mehta, whose telephone number is (703) 306-4540. The Examiner can normally be reached Monday-Friday, from 8:30 A.M. - 5:00 P.M. The fax phone number for the group is (703) 305-3014. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909. Any inquiry of a general nature or relating to the status of the application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Ashwin D. Mehta

August 13, 1999

L. F. Smith

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